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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,580	11/03/2000	Janet Cunningham	0800-0022	6169

20855 7590 01/15/2002  
ROBINS & PASTERNAK LLP  
90 MIDDLEFIELD ROAD  
SUITE 200  
MENLO PARK, CA 94025

EXAMINER
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SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 01/15/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/706,580

Applicant(s)

CUNNINGHAM JANET

Examiner

Lauren Nguyen

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-29 is/are allowed.
- 6) ☒ Claim(s) 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Notice to Comply Requirements*.

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group V, claims 24-29, in Paper No. 9 is acknowledged.

### *Sequence Disclosure Within Specification*

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant is directed to the nucleotide and/or amino acid sequences listed on pages 30 and 31, for example. Applicant is notified to review the entire application for compliance to the sequence rules set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2).

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

*A person shall be entitled to a patent unless –*

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

3. Claims 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by WO

97/38117.

Claim 24 is drawn to a method of inducing gene expression in a mammalian cells comprising (a) transducing the mammalian cell with (i) a first recombinant AAV virion comprising an AAV vector comprising a transcriptional promoter region operably linked to a polynucleotide of interest, wherein the transcriptional promoter region comprises at least one EcRE (ecdysone-responsive element) and a promoter capable of directing the *in vivo* transcription of said polynucleotide of interest in a mammalian cells, located downstream of the at least one EcRE; and (ii) a second recombinant AAV virion comprising an AAV vector that comprises a coding sequence encoding an EcR (ecdysone receptor) operably linked to control elements capable of directing the *in vivo* transcription of said EcR coding sequence in a mammalian cell; and (b) providing ecdysone, or an analog thereof capable of binding the EcR, to said mammalian cell, in an amount sufficient to induce expression of the polynucleotide of interest.

WO 97/38117 discloses a method of inducing expression of an exogenous gene in a mammalian subject containing (i) a DNA construct comprising an exogenous gene under the control of an EcRE, (ii) DNA encoding an EcR under the control of an inducible promoter and, optionally in the further presence of a receptor capable of acting as a silent partner therefore, binds to said EcRE, and (iii) a ligand for said EcR (see p. 26, lines 16-). WO 97/38117 also discloses the delivery of the above mentioned DNA in "suitable retroviral vectors for use herein are described, for example in U.S. Patent 5,252,479..." U.S. Patent 5,252,479 discloses recombinant AAV virions and AAV vectors appropriate for gene therapy applications. Additionally, WO 97/38117 discloses the above mentioned silent partners to be "provided to the

subject by introducing DNA construct(s) encoding receptor into the subject (p. 19, lines 5-) and a preferred silent partner for use in the (disclosed method) is RXR."

Therefore, the invention of the above claims is anticipated by WO 97/38117.

***Allowable Subject Matter***

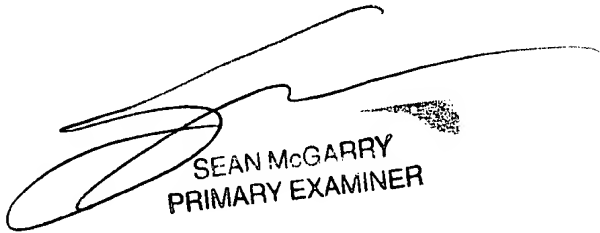
4. Claims 26-29 are allowable. The closest prior art is WO 97/38117 which does not teach a transcriptional promoter region comprising of five EcRe's (ecdysone responsive element) positioned upstream of a Hsp promoter sequence (heat shock protein).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Nguyen, Ph.D. whose telephone number is 703-308-0256. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
SEAN MCGARRY  
PRIMARY EXAMINER

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Lauren Nguyen, Ph.D.

January 10, 2002